

NACERA® Pearl Q³

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

Date of issue: 8/7/2017

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Version: 2.01

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name : NACERA® Pearl Q³

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture : Medical device

1.2.2. Uses advised against

Restrictions on use : For professional use only

1.3. Details of the supplier of the safety data sheet

Supplier

DOCERAM Medical Ceramics GmbH
Heßlingsweg 65-67
44309 Dortmund - Germany
T +49-231-92 56 68-0 - F +49-231-92 56 68-60

Email competent person

sds@kft.de

Other

Informing department: See supplier/manufacturer

1.4. Emergency telephone number

Emergency number : National Health Service (NHS)
24 hour national number consumer
England and Scotland: 111
Wales: 0845 46 47
Northern Ireland: call your local General Practitioner

Call 999 if there is a life-threatening incident.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis.

2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Comments : Zirconium oxide ceramics in pre-sintered discs

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|-------------------|---|-------|---|
| zirconium dioxide | (CAS-No.) 1314-23-4 (EC-No.) 215-227-2 | >= 90 | Not classified |

Comments : Article
Upon machining (e.g. grinding) dust may be formed (see chapter 8).

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For further components with national limit values which require monitoring at the workplace please see chapter 8.

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.
- First-aid measures after inhalation : Measures in case of dust release. Remove person to fresh air and keep comfortable for breathing.
- First-aid measures after skin contact : Wash skin with plenty of water.
- First-aid measures after eye contact : Direct eye contact is unlikely. Dust from this product may cause eye irritation. Rinse opened eye for several minutes under running water. Then consult doctor.
- First-aid measures after ingestion : Ingestion unlikely. Call a poison center or a doctor if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/effects after inhalation : Dust from this product may cause respiratory irritation.
- Symptoms/effects after skin contact : Dust from this product may cause skin irritation.
- Symptoms/effects after eye contact : Dust from this product may cause eye irritation.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Not combustible. Use extinguishing media appropriate for surrounding fire.
- Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

- Hazardous decomposition products in case of fire : None.

5.3. Advice for firefighters

- Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
- Other information : Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Avoid dust formation. Do not breathe dust.

6.1.1. For non-emergency personnel

- Emergency procedures : Ventilate spillage area.

6.1.2. For emergency responders

- Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid sub-soil penetration. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.
- Other information : Disposal must be done according to official regulations.

6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Additional hazards when processed : Manipulations are to be done only by qualified and authorised persons. Extraction to remove dust at its source.
- Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.
- Hygiene measures : Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Always wash hands after handling the product.

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Store in a dry place. Protect from light.

Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Local exhaust is recommended where dust may occur.

Hand protection:

In case of repeated or prolonged contact wear gloves. EN 374. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

Eye protection:

In case of dust production: protective goggles

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. EN 143. EN 149. If dust are formed : Short term exposure, Breathing apparatus with filter, P2.

Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not breathe dust. Avoid contact with skin and eyes. Do not eat, drink or smoke when using this product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|--|---------------------------|
| Physical state | : Solid |
| Appearance | : disc-shaped work piece. |
| Colour | : white. |
| Odour | : odourless. |
| Odour threshold | : Not applicable |
| pH | : Not applicable |
| Relative evaporation rate (butylacetate=1) | : No data available |
| Melting point | : No data available |
| Freezing point | : Not applicable |
| Boiling point | : No data available |
| Flash point | : Not applicable |
| Auto-ignition temperature | : Not self-igniting |
| Decomposition temperature | : No data available |
| Flammability (solid, gas) | : No data available |
| Vapour pressure | : Not applicable |
| Relative vapour density at 20 °C | : No data available |
| Relative density | : No data available |
| Solubility | : Water: Insoluble |
| Log Pow | : Not applicable |
| Viscosity, kinematic | : Not applicable |

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| | |
|----------------------|-----------------------------|
| Viscosity, dynamic | : Not applicable |
| Explosive properties | : Product is not explosive. |
| Oxidising properties | : Non oxidizing. |
| Explosive limits | : Not applicable |

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

| | |
|-----------------------------------|---|
| Acute toxicity (oral) | : Not classified (Based on available data, the classification criteria are not met) |
| Acute toxicity (dermal) | : Not classified (Based on available data, the classification criteria are not met) |
| Acute toxicity (inhalation) | : Not classified (Based on available data, the classification criteria are not met) |
| Skin corrosion/irritation | : Not classified (Based on available data, the classification criteria are not met) pH: Not applicable |
| Additional information | : Dust from this product may cause skin irritation |
| Serious eye damage/irritation | : Not classified (Based on available data, the classification criteria are not met) pH: Not applicable |
| Additional information | : Dust from this product may cause eye irritation |
| Respiratory or skin sensitisation | : Not classified (Based on available data, the classification criteria are not met) |
| Germ cell mutagenicity | : Not classified (Based on available data, the classification criteria are not met) |
| Carcinogenicity | : Not classified (Based on available data, the classification criteria are not met) |
| Reproductive toxicity | : Not classified (Based on available data, the classification criteria are not met) |
| STOT-single exposure | : Not classified (Based on available data, the classification criteria are not met) |
| STOT-repeated exposure | : Not classified (Based on available data, the classification criteria are not met) |
| Aspiration hazard | : Not classified (Not relevant) |

SECTION 12: Ecological information

12.1. Toxicity

| | |
|--------------------------|---|
| Acute aquatic toxicity | : Not classified (Based on available data, the classification criteria are not met) |
| Chronic aquatic toxicity | : Not classified (Based on available data, the classification criteria are not met) |

12.2. Persistence and degradability

| | |
|--------------------------------------|--|
| NACERA® Pearl Q³ | |
| Persistence and degradability | Not applicable. |
| zirconium dioxide (1314-23-4) | |
| Persistence and degradability | Not applicable for inorganic substances. |

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12.3. Bioaccumulative potential

| | |
|------------------------------------|-----------------|
| NACERA® Pearl Q³ | |
| Log Pow | Not applicable |
| Bioaccumulative potential | Not applicable. |

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

| | |
|--|---|
| NACERA® Pearl Q³ | |
| This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII | |
| This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII | |
| Component | |
| zirconium dioxide (1314-23-4) | This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII |

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not dispose of with domestic waste. Do not discharge into drains or the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

| ADR | IMDG | IATA | ADN | RID |
|---|----------------|----------------|----------------|----------------|
| 14.1. UN number | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| 14.2. UN proper shipping name | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| 14.3. Transport hazard class(es) | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| 14.4. Packing group | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| 14.5. Environmental hazards | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| No supplementary information available | | | | |

14.6. Special precautions for user

- Overland transport

Not applicable

- Transport by sea

Not applicable

- Air transport

Not applicable

- Inland waterway transport

Not applicable

- Rail transport

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

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Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Other information, restriction and prohibition regulations : A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

Version/s 1.00 - 2.00 is/are not available in this language.

Abbreviations and acronyms:

| | |
|-------|---|
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| ATE | Acute Toxicity Estimate |
| BCF | Bioconcentration factor |
| CLP | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 |
| DMEL | Derived Minimal Effect level |
| DNEL | Derived-No Effect Level |
| DPD | Dangerous Preparations Directive 1999/45/EC |
| DSD | Dangerous Substances Directive 67/548/EEC |
| EC50 | Median effective concentration |
| IARC | International Agency for Research on Cancer |
| IATA | International Air Transport Association |
| IMDG | International Maritime Dangerous Goods |
| LC50 | Median lethal concentration |
| LD50 | Median lethal dose |
| LOAEL | Lowest Observed Adverse Effect Level |
| NOAEC | No-Observed Adverse Effect Concentration |
| NOAEL | No-Observed Adverse Effect Level |
| NOEC | No-Observed Effect Concentration |
| OECD | Organisation for Economic Co-operation and Development |
| PBT | Persistent Bioaccumulative Toxic |
| PNEC | Predicted No-Effect Concentration |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail |
| SDS | Safety Data Sheet |
| STP | Sewage treatment plant |
| TLM | Median Tolerance Limit |
| vPvB | Very Persistent and Very Bioaccumulative |

Data sources : ECHA (European Chemicals Agency). Information provided by the manufacturer.

Department issuing data specification sheet: : KFT Chemieservice GmbH
Im Leuschnerpark. 3 64347 Griesheim
Postfach 1451 64345 Griesheim
Germany

Phone: +49 6155-8981-400 Fax: +49 6155 8981-500
Safety Data Sheet Service: +49 6155 8981-522

Contact person : Dr. Johann Klassen

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This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product